Supreme Court, U.S.
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No. ____ OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1996

DEBORAH EDDY AND THOMAS EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG, INC. AND DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

PETITION FOR WRIT OF CERTIORARI

JOEL PERSKY, Esquire
Counsel of Record

DAVID B. RODES
GOLDBERG, PERSKY, JENNINGS & WHITE, P.C.
1030 Fifth Avenue
Pittsburgh, PA 15219
(412) 471-3980

Counsel for Petitioner

Of Counsel:
HARLAN S. STONE
STONE & STONE
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219
(412) 391-2005

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) mandates pre-emption of all state law causes of action for injuries caused by medical devices which have received pre-market approval from the Food and Drug Administration?

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PETITION FOR A WRIT OF CERTIORARI

Deborah Eddy and Thomas Eddy respectfully petition for a writ of certiorari to review the judgment of the Superior Court of Pennsylvania in this case.

OPINIONS BELOW

The Opinions of the Superior Court of Pennsylvania (App. 1-7) and the Court of Common Pleas of Allegheny County (App. 8-12) are unreported.

JURISDICTION

The judgment of the Superior Court of Pennsylvania was entered on December 5, 1995. The Supreme Court of Pennsylvania denied a timely Petition for Allowance of Appeal on March 31, 1997. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257(a).

STATUTE INVOLVED

21 U.S.C. § 360k(a) provides that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

STATEMENT OF THE CASE

Petitioner Deborah Eddy sustained serious injuries to her right eye from an infection, acanthamoeba keratitis, as a result of disinfecting her gas permeable contact lenses in accordance with faulty instructions which accompanied her contact lens cleaning system.[1] The lens cleaner and conditioning solution which comprised the cleaning system constituted "Class III medical devices" which had received pre-market approval from the Food and Drug Administration ("FDA") pursuant to the Medical Device Amendments[2] (the "MDA") to the Federal Food, Drug and Cosmetic Act.[3]

Mrs. Eddy and her husband, Petitioner Thomas Eddy, brought suit in the Court of Common Pleas of Allegheny County, Pennsylvania against Respondents, the manufacturer and sellers of the cleaning system,[4] asserting claims for negligence, strict liability and breach of warranty.

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[1] The written instructions provided with the cleaning system call for rinsing the contact lenses with tap water, a procedure which, Petitioners have alleged, foreseeably resulted in Mrs. Eddy's eye infection.

[2] 21 U.S.C. §§ 360c-3601 (1988).

[3] 21 U.S.C. §§ 301-395 (1988).

[4] The cleaning system, consisting of "Boston Advance Cleaner" and "Boston Advance Conditioning Solution", was manufactured and distributed by Respondent Polymer

The Court of Common Pleas, per McFalls, J., granted summary judgment in favor of Respondents,[5] holding that all of Petitioners' claims are pre-empted by the MDA. The court reasoned that

> The product involved in the instant action carries a Class III classification under federal regulations. As such, the lens cleaner and solution require pre-market approval by the FDA. Because pre-market approval is required, the MDA preempts state tort law claims. (App. 12)

The Pennsylvania Superior Court, per Rowley, P.J., Tamilia, J. and Hester, J., affirmed,[6] deeming itself bound by the earlier decision of a panel of that court in *Green v. Dolsky*.[7] (App. 4-5) The Pennsylvania Supreme Court, having affirmed the Superior Court's decision in *Green* in the interim, denied Petitioners' request for discretionary review.[8]

Technology Corporation, a wholly-owned subsidiary of Bausch & Lomb, Inc. A kit containing Boston Advance cleaner and solution was included with the contact lenses which Mrs. Eddy purchased from Respondent Dr. James H. Letham, O.D., and Mrs. Eddy purchased additional bottles of Boston Advance cleaner and solution from Respondent Thrift Drug, Inc.

[5] The October 20, 1994 Opinion of the Court of Common Pleas is set forth at App. 8-12.

[6] The December 5, 1995 Opinion of the Superior Court is set forth at App. 1-7.

[7] 641 A.2d 600 (Pa. Super. 1994), *aff'd*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997).

[8] The March 30, 1997 Order of the Pennsylvania Supreme Court is set forth at App. 13.

REASONS FOR ALLOWANCE OF THE WRIT

In *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), this Court held that the MDA does not pre-empt most state tort law claims for injuries caused by medical devices excused from pre-market approval under the MDA due to "substantial equivalence" with pre-existing devices. Appellate courts in several jurisdictions have since held that the reasoning of *Medtronic* indicates that common law claims for injuries from devices which have received pre-market approval are also not pre-empted by the MDA. However, the Pennsylvania courts hold that pre-market approval automatically results in pre-emption of state law claims.

I. The Pennsylvania Courts' Interpretation of the MDA Preemption Provision is in Conflict With the Decisions of Other Jurisdictions.

The decisions of the Pennsylvania courts in this case and in *Green, supra* n.7, squarely conflict with the decisions of courts of last resort[9] in at least three states which have held that pre-market approval does not mandate pre-emption of common law claims. *See Kernats v. Smith Industries Medical Systems, Inc.*, 669 N.E.2d 1300 (Ill. Ct. App.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *petition for cert. filed* (Mar. 4, 1997) (No. 96-1405);[10] *Fiore v. Collagen*

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[9] These cases are deemed to be decided by "courts of last resort" because the highest courts of the states involved have denied discretionary review.

[10] This Court has invited the Solicitor General to file a brief in the *Kernats* case expressing the views of the United States. *See*

Corp., 930 P.2d 477 (Ariz. Ct. App. 1996), *review denied*, No. CV-96-044-PR (Jan. 14, 1997), *petition for cert. filed* (Apr. 10, 1997);[11] *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 1996), *review denied*, 1997 Cal. LEXIS 833 (Feb. 19, 1997).[12] In addition, intermediate appellate courts of several other states have held that claims relating to devices which have received pre-market approval are not pre-empted. *See Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16 (App. Div. 1997); *Hernandez v. Coopervision, Inc.*, 691 So. 2d 639 (Fla. Dist. Ct. App. 1997); *Walker v. Johnson & Johnson Vision Products, Inc.*, 552 N.W.2d 679 (Mich. App. 1996).[13]

The decision in this case is also contrary to the decision of the Ninth Circuit in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996). Although *Kennedy* was decided before *Medtronic*, the Ninth Circuit subsequently held that its "prior decisions narrowly construing the MDA's preemption clause", including *Kennedy*, "are consistent with

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Kernats v. Smith Industries Medical Systems, Inc., 137 L. Ed. 2d 817 (May 12, 1997).

[11] *Fiore* was decided by the Arizona Court of Appeals one day before this Court's decision in *Medtronic*; all other cases cited in this paragraph were decided after *Medtronic*.

[12] *But cf. Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 1997) (criticizing *Armstrong*). Because the Supreme Court of California has not denied discretionary review in *Steele*, it is not a decision of a court of last resort.

[13] *Sowell*, *Hernandez* and *Walker* each involved contact lenses, whose safety characteristics, and resulting pre-market approval process and labeling requirements, overlap those of lens cleaners and conditioning solutions.

Medtronic". *Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, 92 F.3d 807, 812 (9th Cir. 1996), *cert. denied*, 117 S. Ct. 754 (1997).[14]

The Pennsylvania courts' interpretation of the MDA is at odds with various other courts' interpretations of the same federal statute. Certiorari is therefore appropriate to restore the uniform application of federal law.

II. The Pennsylvania Courts' Interpretation of the MDA Preemption Provision is in Conflict With the Reasoning of This Court's Medtronic Decision.

Although *Medtronic* did not involve a device which had received pre-market approval, it established a framework for analysis of 21 U.S.C. § 360k(a) which is generally applicable to all MDA pre-emption claims. Two features of the majority's analysis are particularly pertinent here:

First, the Court held that the MDA pre-emption provision is ambiguous, and that the FDA's interpretation is therefore to be accorded substantial weight. *See*

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[14] *But cf. Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997) ("to the extent we concluded in *Kennedy* that the MDA cannot preempt *any* state common-law causes of action, the conclusion cannot survive in light of the concurring and dissenting opinions in *Medtronic*") (emphasis in original). *Papike* concerned a Class II device which was subject to a specific, affirmative labeling regulation. *See id.* at 739. It did not repudiate *Kennedy*'s holding that pre-market approval of Class III devices does not require pre-emption of common law claims.

Medtronic, 116 S. Ct. at 2255-56 (Stevens, J., for the Court)[15] ("[T]he FDA . . . is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be pre-empted. . . . The ambiguity in the statute – and the congressional grant of authority to the agency on the matter contained within it – provide a 'sound basis' . . . for giving substantial weight to the agency's view of the statute.") (citations omitted).[16]

The FDA has consistently taken the position that the MDA does not pre-empt tort claims based on generally applicable duties. Thus, the FDA has promulgated regulations which "note that the statute is not intended to pre-empt 'State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices. . . . ' " *Id.* at 2257, quoting 21 CFR § 808.1(d)(1) (1995).

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[15] Justices Kennedy, Souter and Ginsburg concurred in Justice Stevens's opinion in its entirety. Justice Breyer concurred in Parts I-III, V and VII of Justice Stevens's opinion. The passages cited here are drawn from Part V, in which a majority of the Court concurred.

[16] *See also* 116 S. Ct. at 2260-61 (Breyer, J., concurring) ("[T]he MDA's pre-emption provision is highly ambiguous. . . . [C]ourts may infer that the relevant administrative agency possesses a degree of leeway to determine which . . . administrative actions will have pre-emptive effect. . . . At least in present circumstances, no law forces the FDA to make its requirements pre-emptive if it does not think it appropriate.").

In contrast to this Court's careful consideration of the FDA's position, the Pennsylvania courts have accorded that position virtually no weight. The opinions in this case do not mention the FDA's interpretation; the prior decision on which the Superior Court relies in this case mentions the FDA's position only to reject it. *See Green*, 641 A.2d at 606 ("[W]e view the FDA opinion letter as merely advisory and not dispositive.").

Second, in keeping with the FDA's interpretation, this Court held in *Medtronic* that common law labeling or warning requirements are not pre-empted under the MDA:

> [T]he general state common-law requirements in this case were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. . . . [T]he predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. . . . These state requirements therefore escape pre-emption, . . . because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices. . . . As a result, none of the Lohrs' claims based on allegedly defective . . . labeling are pre-empted by the MDA.

116 S. Ct. at 2258 (Stevens, J., for the Court).

Although pre-market approval is more rigorous than the substantial equivalence review at issue in *Medtronic*, differences in the FDA procedures affect only the nature

of the federal requirements, and have no bearing on whether the state requirements are "with respect to" the device in question. The "generality" or "general applicability" of a state law requirement such as the duty to warn of known latent dangers is not affected by the specificity of any federal requirement. Consequently, under the reasoning of *Medtronic* and the FDA regulations embraced therein, general state law tort claims are not pre-empted.

By focusing solely on the nature of the federal requirements and disregarding the generality of the state requirements, the Pennsylvania courts have adopted an interpretation of the MDA which is contrary to the reasoning of this Court. Certiorari is appropriate to correct the Pennsylvania courts' continuing error.

III. Whether Pre-Market Approval Insulates Manufacturers of Medical Devices from Tort Liability is an Important Issue.

A holding that state law claims are pre-empted by virtue of a product's pre-market approval has the "effect of granting complete immunity from design defect liability" for that product, and thus "remov[ing] all means of judicial recourse for those injured" thereby. *See Medtronic*, 116 S. Ct. at 2251 (Stevens, J., plurality opinion). The broad immunity accorded by the Pennsylvania courts' interpretation would undermine the important role of state tort law in encouraging product safety and distributing losses among product users. *See generally Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) ("[P]ublic policy demands

that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business.").

Although most new Class III medical devices presently avoid pre-market approval by means of the substantial equivalence process, manufacturers will more readily undergo the pre-market approval process if it is held to insulate them from liability for injuries caused by their products. Moreover, the already substantial number of court cases involving pre-market approval will certainly grow as new devices are developed which are not equivalent to pre-existing devices. Resolution of the preemption issue may therefore control the outcome of numerous cases affecting many people and products.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

JOEL PERSKY, Esquire
Counsel of Record

Of Counsel:
HARLAN S. STONE
STONE & STONE
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219
(412) 391-2005

DAVID B. RODES
GOLDBERG, PERSKY, JENNINGS
& WHITE, P.C.
1030 Fifth Avenue
(412) 471-3980
Counsel for Petitioner

DEBORAH EDDY AND THOMAS EDDY, Appellants v. POLYMER TECHNOLOGY CORP., THRIFT DRUG, INC., AND DR. JAMES LETHAM, O.D.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA NO. 1941 PITTSBURGH 1994

Appeal from the Order Entered October 20, 1994, Docketed October 21, 1994, in the Court of Common Pleas of Allegheny County, Civil Division, No. GD 92-16038.

DEBORAH EDDY AND THOMAS EDDY, Appellants v. POLYMER TECHNOLOGY CORP., THRIFT DRUG, INC., AND DR. JAMES LETHAM, O.D.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA NO. 1942 PITTSBURGH 1994

Appeal from the Order Entered October 20, 1994, in the Court of Common Pleas of Allegheny County, civil Division, No. GD 92-16038.

BEFORE: ROWLEY, P.J., and TAMILIA and HESTER, JJ.

MEMORANDUM: Filed: December 5, 1995

We are asked in this appeal to decide if the trial court properly granted summary judgment to appellees after concluding that appellants' claims were preempted by the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA). After careful review of the trial court's reasoning and the arguments raised by both parties herein, we affirm.

Appellant Deborah Eddy filed a claim against appellees Polymer Technology Corporation (Polymer), Thrift Drug, Inc. (Thrift), and Dr. James H. Letham, O.D. (Dr. Letham) after contracting an eye infection allegedly caused by inadequate instructions regarding the proper method of disinfecting her gas permeable contact lenses. She sought damages from both the corporate defendants and Dr. Letham individually under theories of negligence, strict liability, breach of implied warranty, and, on behalf of Thomas Eddy, a loss of consortium. Relying on this Court's decision in *Green v. Dolsky*, 433 Pa.Super. 556, 641 A.2d 600 (1994), *appeal granted*, 539 Pa. 678, 652 A.2d 1324 (1994), the trial court granted appellees' motions[1] for

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[1] The trial court issued two orders, both filed on October 20, 1994. The first granted summary judgment in favor of appellees Polymer and Thrift. The second granted summary judgment in favor of appellee Dr. Letham. Appellants' appeals of both orders were consolidated on December 21, 1994.

summary judgment[2] on the basis that appellants' claims were preempted by federal law, specifically that portion of the MDA which controls regulation of Class III medical devices. 21 U.S.C. § 360k.

Any discussion regarding whether a cause of action under common law is preempted by federal statute begins with a strong presumption against preemption. *Mazaike v. Bank One, Columbus, N.A.*, 439 Pa.Super. 95, 653 A.2d 640 (1994), *appeal granted*, ___ Pa. ___, 659 A.2d 557 (1995). However, preemption will be found where: 1) Congress' intent to preempt a field is expressly stated; 2) state law is preempted by virtue of a conflict with federal law; or 3) the federal law at issue so thoroughly occupies a field as to leave no doubt with respect to Congress' intent that state law may not supplement federal law on the subject. *Green, supra.* State regulation to which preemption applies is not limited to express regulatory actions taken by a state, but "can be effectively exerted through an award of damages[,]" which may have the result "of governing conduct and controlling policy." *Cipollone v. Liggett Group, Inc.*, 504 U.S. ___, ___, 112 S.Ct. 2608, 2620, 120 L.Ed.2d 407 (1992), *quoting San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247, 79 S.Ct. 773, 780, 3 L.Ed.2d 775 (1959).

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[2] Summary judgment is proper, under Rule 1035, when a review of the pleadings, depositions, answers to interrogatories, admissions on file and supporting affidavits demonstrate that there is no genuine issue of material fact, and the movant is entitled to summary judgment as a matter of law. Pa.R.C.P. 1035(a); *Marks v. Tasman*, 527 Pa. 132, 589 A.2d 205 (1991).

The facts presented by this case are essentially identical to those presented in *Green, supra.* In *Green* this Court was confronted with claims for damages resulting from collagen treatments. The plaintiff asserted the same causes of action as have been asserted by appellants in this case, all of which, as here, were presented within the context of the identical provision of the MDA.[3] *Id.* at 558, 641 A.2d at 602. As was the case in *Green,* there is no dispute in this case that the products involved are classified as Class III medical devices. As such, they are subject to the most stringent oversight authorized by regulations promulgated under the FDCA. *King v. Collagen Corp.,* 983 F.2d 1130 (1st Cir. 1993). In affirming the trial court's grant of summary judgment in favor of defendant Collagen Corporation in *Green,* this Court determined that "a finding in favor of [appellants] on any of their alleged state tort law claims would impose additional or different

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[3] Title 21 U.S.C. § 360k provides:

§ 360k State and Local Requirements Respecting Devices.

(a) General Rule

Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement.

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.

requirements on [appellee] . . . whose product . . . has already received FDA approval. Such requirements are in conflict with the MDA and thus, the [appellants'] state law claims are therefore preempted." *Id.* at 567, 641 A.2d at 605. Contrary to appellants' assertions, we are bound by prior decisions of this Court. *Lower Paxton Township v. U.S. Fid. & Guar. Co.*, 383 Pa.Super. 558, 573, 557 A.2d 393, 400 (1989). Therefore, we conclude, as did the trial court, that summary judgment in favor of Polymer and Thrift, on the basis that federal law preempted appellants' state tort law claims, was proper.

There is a distinction between this case and *Green*, however, which requires discussion. In *Green*, "[t]he sole issue on appeal [was] whether the trial court erred in granting summary judgment in favor of [the manufacturer] Collagen[.]" *Green*, 433 Pa.Super. at 559, 641 A.2d at 602. Here, appellants claim the trial court erred in granting summary judgment in favor of Dr. Letham, as well as the corporate defendants, Polymer and Thrift.[4]

Appellants' complaint alleged three causes of action against Dr. Letham: negligence, breach of implied warranty, and strict liability. However, we note from the

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[4] Subsequent to this Court's decision in *Green*, the Court of Appeals for the Third Circuit had occasion to address the issue of federal preemption of state law causes of action in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3rd Cir. 1994), *cert. denied*, ___ U.S. ___, 115 S.Ct. 429, ___ L.Ed.2d ___ (1994). The Court of Appeals concluded that while the appellant's state tort law remedies against the manufacturer of an intraocular lens implant device were "displaced" by the provisions of the MDA, she was free to assert a right of redress in state court against her physician. *Id.* at 546.

record that appellants' response to appellees' motions for summary judgment, as well as the accompanying brief, are entirely devoted to an argument generally addressing the issue of whether state law causes of action are pre-empted by federal law. There is not a single reference to the causes of action brought individually against Dr. Letham. Similarly, the trial court's opinion does not distinguish the reasons it granted summary judgment to Polymer and Thrift from those it relied upon in granting summary judgment to Dr. Letham. Furthermore, appellants' appellate brief fails to provide a single argument that draws a distinction between the alleged impropriety of the trial court's grant of summary judgment in favor of Polymer and Thrift, as opposed to that granted Dr. Letham. The only argument appellants advance with respect to Dr. Letham appears in appellants' reply brief and is directed solely to a claim that Pennsylvania case law does not preclude a strict liability claim against Dr. Letham. That issue was specifically addressed by this Court in *Cafazzo v. Central Medical Health Services, Inc.*, 430 Pa.Super. 480, 635 A.2d 151 (1993), *appeal granted*, 538 Pa. 608, 645 A.2d 1311 (1994), and was found to be without merit.[5]

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[5] Appellant's reply brief relies on the fact that the Supreme Court granted allocatur in *Cafazzo*. Appellants apparently equate the grant of allocatur with a reversal. We decline to presume how the Supreme Court will rule, or when, and say again that we are bound by prior decisions of this Court. This Court's decision in *Cafazzo* is dispositive of appellants' claim that a strict product liability action against Dr. Letham is not precluded under Pennsylvania case law. It is, *Cafazzo*, 430 Pa.Super. at 488, 635 A.2d at 155 (a physician is not a "seller" under 402A, Restatement of Torts, and therefore is not subject to

Viewing all the evidence in a light most favorable to appellants, we cannot agree that the trial court committed an error of law or abused its discretion in granting summary judgment in favor of appellees Polymer and Thrift on the grounds of federal preemption. *Green, supra.* Dr. Letham is not subject to a claim for damages under a theory of strict product liability. *Cafazzo, supra.* Furthermore, appellants have waived any claims that the trial court erred in granting summary judgment in favor of Dr. Letham on the negligence and breach of implied warranty causes of action for failure to argue them in their brief. Pa.R.A.P. 2119; *Harvilla v. Delcamp,* 521 Pa. 21, 555 A.2d 763 (1989), *citing Commonwealth v. Jackson,* 494 Pa. 457, 431 A.2d 944 (1981).[6] Accordingly, we affirm the orders entered on October 20, 1994.

Orders affirmed.

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a claim for strict product liability); *see also Bigansky v. Thomas Jefferson University Hosp.,* ___ Pa.Super. ___, 658 A.2d 423 (1995).

[6] We are not unaware that a recent decision of this Court affirmed a trial court's denial of preliminary objections, on the grounds that common law liability was not preempted by the provisions of the National Traffic and Motor Vehicle Safety Act (the Safety Act), 15 U.S.C. § 1381 *et seq. Heiple v. C.R. Motors Inc., and G.M. Corp.,* ___ Pa.Super. ___, ___ A.2d ___ (1995) (No. 808 Pittsburgh 1994, filed 7/31/95). The panel concluded that the savings clause included in the Safety Act expressly "does not exempt a person from liability at common law," 49 U.S.C. § 30103(e), and thus, common law causes of action were preserved. We distinguish *Heiple* on the basis that a different federal statute was at issue: "[t]he MDA [unlike the Safety Act] does not contain a savings clause expressly precluding exemption from liability under state common law." *Heiple,* ___ Pa.Super. at ___, ___ A.2d ___ at 34.

IN THE COURT OF COMMON PLEAS OF
ALLEGHENY COUNTY, PENNSYLVANIA
CIVIL ACTION - LAW

DEBORAH EDDY and THOMAS EDDY,

Plaintiffs,

vs.

POLYMER TECHNOLOGY CORPORATION; THRIFT DRUG, INC. and JAMES H. LETHAM, O.D.,

Defendants.

No. G.D. 92-16038

OPINION

Plaintiffs filed suit against defendants for injuries sustained from an infection contracted by wife-plaintiff and allegedly caused by the wife-plaintiff's disinfection of gas permeable contact lenses. The action is based on counts of negligence, strict liability, breach of warranty and loss of consortium.

In the complaint, plaintiffs allege that wife-plaintiff, a patient of Dr. Letham, purchased from him a gas permeable contact lens manufactured and distributed by Polymer. A user kit was included with the lens. The kit contained a bottle of Advance Conditioning Solution and Advance Cleaner supplied by Polymer bearing the "Boston" trademark. (Polymer is a wholly owned subsidiary of Bausch & Lomb, Inc.).

Wife-plaintiff then at the same time, purchased a bottle of contact lens cleaner and contact lens conditioning solution from Thrift Drug and manufactured and distributed by Polymer.

After using the cleaner and conditioning solution, wife-plaintiff developed an eye infection diagnosed as Acanthamoeba Keratitis. The infection was allegedly caused from rinsing the lens with tap water after cleaning. According to the complaint, wife-plaintiff cared for her lens in accordance with the instructions given to her by Dr. Letham and those which were distributed along with the cleaner and conditioning solution by Polymer and sold by Dr. Letham and Thrift Drug.

Defendants filed Motions for Summary Judgment which were granted by orders of court of the Honorable Patrick McFalls on October 20, 1994.

Defendants moved for Summary Judgment based on the argument that plaintiffs' state tort law claims are preempted by federal law.

Pa. R.C.P. 1035 states in relevant part:

> (a) After the pleadings are closed . . . any party may move for summary judgment on the pleadings and any depositions, answers to interrogatories, admissions on file and supporting affidavits.
>
> (b) The judgment sought shall be rendered if the pleadings, depositions, answer to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. . . .

In considering a Motion for Summary Judgment, the court must view the record in the light most favorable to the non-movant. Only where the pleadings, answers to interrogatories, depositions, admissions and affidavits establish that the movant's right to relief is clear and free from doubt should a court grant a summary judgment. *McNeal v. City of Eastron,* 143 Commw. Ct. 151, 598 A.2d 638, 639 (1991). When a Motion for Summary Judgment is made and supported by evidence of record, the non-movant may not rest on his allegations but rather must set forth specific facts of record showing there is a genuine issue for trial. *McNeal* at 639, 640.

In the instant action, summary judgment was properly granted in favor of defendants because federal law pre-empts the plaintiffs' state tort law claims.

21 U.S.C. § 360K provides:

§ 360K State and Local Requirements Respecting Devices

(a) General Rule

Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement –

(1) Which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) Which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Recent decisions from the Superior Court and the United States District Court address the issue present in the case at hand. In the case of *Green v. Dolsky*, 433 Pa. Super. 556, 641 A.2d 600 (1994), the issue before the court was whether the trial court erred in granting Summary Judgment in favor of Collagen on the basis that the MDA preempted the Greens' state tort law claims. The Superior Court considered cases from other jurisdictions, including federal cases, to determine the issue before it. In its opinion the Court stated:

> Generally, pre-emption may be express or implied, and it is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose . . . when Congress is silent on the matter, state law will be preempted by federal law "when (a) compliance with both state and federal law is impossible or, (b) when state law stands as an impediment to a federal purpose". *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744, 747 (M.D. Pa. 1992).

Moreover, the United States District Court in the case of *Gerber, et al. v. Medtronic Inc.*, 142 P.L.J. 396 (1994), when considering a motion for summary judgment in a case involving a Class III product and § 360K (a) stated:

> State requirements relating to the safety and effectiveness of medical devices regulated pursuant to the MDA may include common law tort standards of liability, as well as legislation and administrative regulations. . . . Following the weight of authority, I hold that because plaintiffs' strict liability, negligence, failure to warn and breach of warranties claims with respect to the model No. 4003 lead would impose safety

and effectiveness requirements in addition to the FDCA, they are all preempted by the MDA.

The product involved in the instant action carries a Class III classification under federal regulations. As such, the lens cleaner and solution require pre-market approval by the FDA. Because pre-market approval is required, the MDA preempts state tort law claims.

In the case at hand and in light of federal statutes and regulations and applicable case law, summary judgment was properly granted in favor of the defendants because plaintiffs' state tort law claims are preempted by the MDA.

BY THE COURT,

/s/ McFalls, J.

cc: Harlan S. Stone, Esq.
Robert J. Behling, Esq.
Kerry A. Kearney, Esq.
Joel Persky, Esq.

IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

DEBORAH EDDY AND THOMAS EDDY, Petitioners. v. POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG, INC., AND DR. JAMES H. LETHAM, O.D., Respondents.	:	Nos. 004 and 005 Western District Allocatur Docket 1996 Petition for Allowance of Appeal from Superior Court

ORDER

PER CURIAM:

AND NOW, this 31st day of March, 1997, the Petition for Allowance of Appeal is hereby DENIED.

Supreme Court, U.S.
FILED
JUL 31 1997
CLERK

No. 97-26

In The

Supreme Court of the United States

October Term, 1996

DEBORAH EDDY AND THOMAS EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG CO. AND DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

BRIEF OF RESPONDENT DR. JAMES H. LETHAM, O.D., IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

ROBERT J. BEHLING
Counsel of Record
BRIAN S. KANE
JEANETTE H. HO
PIETRAGALLO, BOSICK & GORDON
One Oxford Centre, 38th Floor
Pittsburgh, PA 15219
(412) 263-2000
Counsel for Respondent Dr. James H. Letham, O.D.

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
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39pp

EDITOR'S NOTE

THE FOLLOWING PAGES WERE POOR HARD COPY AT THE TIME OF FILMING. IF AND WHEN A BETTER COPY CAN BE OBTAINED, A NEW FICHE WILL BE ISSUED.

QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) mandates preemption of state common law claims which seek to impose requirements which would conflict with the requirements imposed by the Food and Drug Administration in the course of the pre-market approval process?

STATEMENT OF THE CASE

Petitioners filed the suit which gives rise to this Petition for Writ of Certiorari on September 9, 1992 seeking to recover for damages allegedly sustained as a result of using contact lens cleaner and solution manufactured by Respondent, Polymer Technology Corporation ("Polymer") and sold by Respondent, Thrift Drug, Inc. ("Thrift Drug"). Wife-Petitioner alleges that she developed acanthamoeba keratitis as a result of rinsing her contact lenses with tap water as required by the directions which accompanied the sale of the cleaner and solution.

Between September 16 and September 25, 1990, Wife-Petitioner was a patient of Respondent, Dr. James H. Letham, an optometrist. Plaintiff was a patient of Dr. Letham for several years prior to this incident. On or about September 16, 1990, Dr. Letham examined the Wife-Petitioner and prescribed a gas permeable right contact lens manufactured by Respondent, Polymer. Dr. Letham fitted the lens and provided Wife-Petitioner with a starter kit supplied to Dr. Letham by Polymer. The starter kit contained small, sample-sized containers of cleaner and solution also manufactured by Polymer. Wife-Petitioner eventually purchased a larger bottle of the cleaner and solution from Thrift Drug.

The cleaner and solution contained explicit instruction for the proper use of the products. These directions were approved by the Food and Drug Administration ("FDA") prior to the introduction of these products into the open market. *See* Affidavit of William Gleason, O.D., which is attached at S.A. 1.

Petitioners have asserted claims of negligence, strict liability and breach of implied warranties against Dr. Letham. Essentially, Petitioners contend that Dr. Letham is liable for failing to warn or instruct the Wife-Petitioner on the use of the cleaner and solution or that she could develop acanthamoeba keratitis through the use of the cleaner and solution manufactured by Polymer.

REASONS WHY THE PETITION FOR WRIT OF CERTIORARI SHOULD BE DENIED

Dr. James Letham is Not a Proper Respondent to this Petition

The only question presented by Petitioners in this Petition for Writ of Certiorari is "[w]hether 21 U.S.C. § 360k(a) mandates preemption of all state law causes of action for injuries caused by medical devices which have received pre-market approval from the Food and Drug Administration?" *See* Petition for Writ of Certiorari, p. i.

By order dated October 24, 1994, the Court of Common Pleas of Allegheny County, Pennsylvania granted summary judgment in favor of Polymer, Thrift Drug and Dr. Letham on the grounds that Petitioners' claims against these parties were preempted by the Medical Device Amendments.

Petitioners filed a notice of appeal to the Superior Court of Pennsylvania from this order. Said notice of appeal stated: "Notice is hereby given that the Plaintiffs, above named, hereby appeal to the Superior Court of

Pennsylvania from the Order granting Summary Judgment to the Defendant(s), **Polymer Technology Corp. and Thrift Drug, Inc.** entered in this matter on the 20th day of October, 1994. This order has been entered into the docket as evidenced by the attached copy of the docket entry." (emphasis added).

While Polymer and Thrift Drug are named in the notice of appeal, Dr. Letham is not named. Furthermore, in the argument presented to the Superior Court of Pennsylvania, the Petitioners completely failed to address the causes of action brought individually against Dr. Letham. *See* Opinion of the Superior Court of Pennsylvania dated December 5, 1995, App. 6. The only time the claims against Dr. Letham were mentioned was in the Petitioners' reply brief where they argued that Dr. Letham could be held strictly liable under Pennsylvania law. *Id.* The Superior Court found this argument to be totally without merit and held that Dr. Letham was not subject to strict liability under Pennsylvania law. *Id.* As a result, the Pennsylvania Superior Court held that the Petitioners had ". . . . waived any claims that the trial court erred in granting summary judgment in favor of Dr. Letham on the negligence and breach of implied warranty causes of action for failure to argue them in their brief." *Id.*

Petitioners, in their Petition for Writ of Certiorari, do not challenge the Superior Court's finding of waiver with respect to their claims against Dr. Letham. They also do not challenge the Superior Court's conclusion that Dr. Letham cannot be held strictly liable under Pennsylvania law. Rather, the only issue which they raise is whether their state law causes of action are pre-empted by 21

U.S.C. § 360k(a). Since the judgment in favor of Dr. Letham was not based on preemption, but on waiver and the application of Pennsylvania state law, Dr. Letham is not a proper party to this Petition for Writ of Certiorari and Certiorari should be denied as to him.

CONCLUSION

Therefore, Respondent, Dr. James H. Letham, respectfully requests that the Petition for Writ of Certiorari be denied.

Respectfully submitted,

PIETRAGALLO, BOSICK & GORDON

ROBERT J. BEHLING, Esquire
BRIAN S. KANE, Esquire
JEANETTE H. HO, Esquire

One Oxford Centre, 38th Floor
Pittsburgh, PA 15219

(412) 263-2000

Counsel for Respondent, Dr. James H. Letham

APPENDIX

IN THE COURT OF COMMON PLEAS OF
ALLEGHENY COUNTY, PENNSYLVANIA
-CIVIL DIVISION-

DEBORAH EDDY and THOMAS EDDY, Plaintiffs, v. POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG INC., and DR. JAMES H. LETHAM, O.D. Defendants.	No. GD 92-16038 Code No. 004 DECLARATION OF WILLIAM GLEASON, O.D., IN SUPPORT OF DEFENDANTS POLYMER TECHNOLOGY CORPORATION AND THRIFT DRUG, DRUG, INC.'S MOTION FOR SUMMARY JUDGMENT Filed on behalf of Polymer Technology Corporation and Thrift Drug, Inc. Counsel of Record for this party: Kerry A. Kearney Pa. I.D. No. 20120 REED SMITH SHAW & McCLAY Firm I.D. No. 234 435 Sixth Avenue Pittsburgh, PA 15219 (412) 288-3046

IN THE COURT OF COMMON PLEAS OF
ALLEGHENY COUNTY, PENNSYLVANIA
-CIVIL DIVISION-

DEBORAH EDDY and THOMAS EDDY, Plaintiffs, v. POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG INC., and DR. JAMES H. LETHAM, O.D. Defendants.	No. GD 92-16038 Code No. 004 DECLARATION OF WILLIAM GLEASON, O.D., IN SUPPORT OF DEFENDANTS POLYMER TECHNOLOGY CORPORATION AND THRIFT DRUG, DRUG, INC.'S MOTION FOR SUMMARY JUDGMENT

I, William Gleason, O.D., declare:

1. I have been employed by Polymer Technology Corporation ("Polymer") since October 1987. From October 1, 1987, until May 1991, I served as Polymer's Director of Clinical and Regulatory Affairs. From May 1991 until January 1994 I was Polymer's Director of Product Development and Quality Affairs. Since January 1994, I have been Polymer's Director of Quality and Regulatory Affairs.

2. As Director of Quality and Regulatory Affairs, my responsibilities include overseeing Polymer's dealings with the Federal Food and Drug Administration ("FDA") in gaining FDA approval of Polymer's products and maintaining the approval status of those products. I am knowledgeable in regulatory practices and various governmental requirements for medical devices, including FDA regulations, concerning approval of medical

devices, post-approval surveillance and good manufacturing practices. I participate on product development teams to determine regulatory requirements for new Polymer products, review safety and efficacy information generated on Polymer products, submit applications to the FDA for pre-market approval for new Polymer products, and respond to FDA review or requests for clarification and additional information during the regulatory review process. Additionally, my department is responsible for reviewing and approving all Polymer label changes to insure compliance with FDA regulations and I manage all approved Polymer products to insure compliance with current regulatory requirements. I am familiar with all documentation regarding FDA approval of Polymer's products.

3. Polymer manufactures and distributes the Boston® line of contact lens solutions designed for use with rigid gas permeable ("RGP") contact lenses. The Boston® Solutions include Boston® and Boston Advance® Cleaners and Conditioning Solutions. The Boston® line of products has been on the market since 1983. The Boston Advance® Cleaner ("Cleaner") has been formulated for daily cleaning of RGP lenses to remove surface deposits which build up during lens wear. The Boston Advance® Conditioning Solution ("Solution") has been formulated to disinfect RGP lenses after cleaning and rinsing and to enhance the wettability characteristics of RGP lenses.

4. The attached package insert and labeling for the Boston Advance® Cleaner recommends that the user "rub lens carefully with several drops of Boston Advance® Cleaner in the palm of your hand for twenty (20) seconds" and then "rinse off thoroughly with fresh

tap water." The directions then tell the user to "place lens in storage case and cover with a fresh supply of Conditioning Solution. Soak for at least 4 hours or overnight before wearing." A true copy of the package insert for the Boston Advance® Cleaner is attached as "Exhibit A." The package insert and labeling for the Boston® Conditioning Solution states that after disinfection with the Conditioning Solution for at least four hours or overnight the user should "reapply fresh Boston Advance® Conditioning Solution if desired and insert." A true copy of the package insert for the Boston Advance® Conditioning Solution is attached as "Exhibit B."

5. In 21 C.F.R. 886.5918 (1993), the FDA classifies rigid gas permeable contact lens solutions as Class III medical devices pursuant to the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act. Pub. L. 94-295, § 2, 90 Stat. 574, amending 21 U.S.C. § 301 *et seq.* (codified at 21 U.S.C. § 360c *et seq.*). Both the Cleaner and the Solution are RGP lens solutions, classified by the FDA pursuant to 21 C.F.R. 886.5918 as Class III medical devices:

> (a) A rigid gas permeable contact lens solution is a device intended to clean, disinfect, wet or store a rigid gas permeable contact lens.
>
> (b) *Classification.* Class III.
>
> (c) *Date PMA or notice of completion of a [Product Development Protocol] is required.* . . . An approval under section 515 of the act is required before this device may be commercially distributed.

21 C.F.R. § 886.5918.

6. Under 21 C.F.R. § 886.3, the FDA requires that the Solution and Cleaner, as Class III medical devices, receive pre-market approval ("PMA") to determine the safety and efficacy of these solutions prior to being marketed or sold by Polymer:

> a device in this part [of the regulation] that is classified into class III (premarket approval) shall not be commercially distributed . . . unless the manufacturer has an approval under section 515 of the act . . . An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval for the device or declaring completed a product development protocol for the device.

21 C.F.R. § 886.3.

7. On September 14, 1989, Polymer submitted detailed applications to the FDA seeking pre-market approval for the Cleaner and detailed applications for the Solution on November 3, 1988. The applications disclosed the proposed directions for use of these products, including directions concerning rinsing the RGP lenses with tap water after use of the Cleaner and prior to disinfection with the Solution. As part of the PMA application process for the Cleaner and Solution, the FDA considered the propriety of all the labeling associated with the products, including tap water rinsing. The cover letters submitted with the applications are attached as "Exhibit C" and "Exhibit D."

8. The PMA applications for the Cleaner and the Solution included information regarding product specifications, intended use, manufacturing methods, and data

from clinical studies conducted of patients using the Boston® Solutions. As part of the review process, the FDA referred Polymer's original PMA applications to the FDA Ophthalmic Devices Panel of the Center of Devices and Radiological Health for review by experts in the ophthalmology.

9. In a letter dated June 1, 1989, the FDA approved a supplemental PMA application for the Solution, stating that "based upon the information submitted, the PMA supplement is approved subject to the conditions described", thereby permitting the Solution to be marketed as a Class III medical device. (Attached as "Exhibit E".) In a letter dated May 3, 1990, the FDA approved the PMA application for the Cleaner, permitting it also to be marketed as a Class III medical device. The approval letter states that "you may begin commercial distribution of the device upon receipt of this letter." (Attached as "Exhibit F".)

10. The FDA approved the PMA application for the original formula Boston® Cleaner and the original formula Boston® Conditioning Solution on November 17, 1983. In this original 1983 PMA, the FDA approved tap water rinsing of RGP lenses.

11. Rinsing of the RGP lenses in tap water prior to disinfection with Boston® products has been approved as safe and effective through the PMA approval process by the FDA three times (1987, 1989, and 1990) since the original 1983 approval.

12. At all times since the products were approved by the FDA as Class III medical devices, Polymer has maintained FDA approval for the Cleaner, Solution, the

original formula Boston® Conditioning Solution, and original formula Boston® Cleaner, including all labeling and directions for use associated with these products.

I declare under penalty of perjury under the laws of the Commonwealth of Pennsylvania pursuant to 18 Pa.C.S.A. § 4904 that the foregoing is true and correct.

/s/ William J. Gleason, O.D.
William J. Gleason, O.D.
Director of Quality &
Regulatory Affairs
Polymer Technology
100 Research Drive
Wilmington, MA 01887

Date: August 2, 1994

LIST OF EXHIBITS

Exhibit A ....Boston Advance® Cleaner Instructions

Exhibit B.....Boston Advance® Conditioning Solution Instructions

Exhibit C.....PMA Cover Letter for Boston Advance® Cleaner

Exhibit D ....PMA Cover Letter for Boston Advance® Conditioning Solution

Exhibit E.....FDA Approval Letter for Boston Advance® Conditioning Solution

Exhibit F.....FDA Approval Letter for Boston Advance® Cleaner

Boston™
ADVANCE
cleaner
For Rigid Gas Permeable
Contact Lenses
not for use with Soft Lenses

See Package Insert for
Lens Lit, Directions, and
Important Safety Information
10 ml • Sterile • Patent Pending
Lot/Exp. Date

Boston Advance Cleaner 10 ml
PMS 222 Magenta
PMS 874 Gold

CONFIDENTIAL

P 2886

LBOU0101	LABELING APPROVAL 58580	
RI	Alex Sato	Date: 5-4-90
. & D	N/A	Date: —
	J. Pomander	Date: 5-4-90
A	Gale Mercaf	Date: 5/4/90
egal	By N/A	Date: —
tem No.	N/A	Supercedes —

EXHIBIT A

[redacted]

POLY001763

BOSTON ADVANCE™ Cleaner

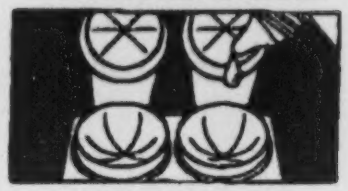
For Fluoro Silicone Acrylate and Silicone Acrylate Rigid Gas Permeable Contact Lenses

DIRECTIONS FOR USE:

1 Wash hands thoroughly.

2 Rub lenses carefully with several drops of BOSTON ADVANCE Cleaner in the palm of your hand for twenty (20) seconds.

3 REMOVE ALL TRACES OF BOSTON ADVANCE CLEANER BY THOROUGHLY RINSING WITH FRESH TAP WATER.



4 Place lens in storage case and cover each lens with a fresh supply of conditioning solution. Soak for at least 4 hours or overnight before wearing.

5 Always keep bottle tightly closed when not in use.

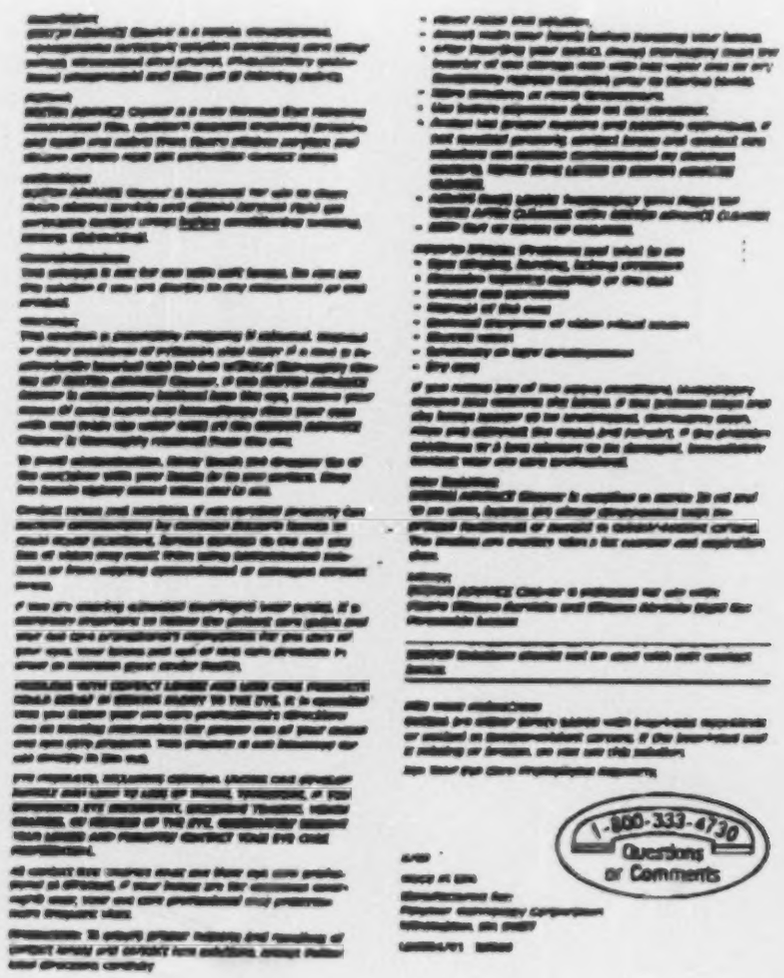
6 Carefully observe warnings and precautions on the following side. Store at room temperature. IMPORTANT: Please read carefully and keep this information for future use.

FRONT

ml
ston Advance Cleaner

DH

POLY001837



BACK

LB6034/01 LABELING APPROVAL 5856		
MKT	L Walworth	Date: 4-20-90
R & D	N/A	Date: —
QA	L Provencher	Date: 4-20-90
RA	Ellen M Beuchler	Date: 4-20-90
Legal	By N/A	Date: —
Item No. N/A		Supercedes —

POLY001836

[redacted]

STON ADVANCE™
CARE SYSTEM

Rigid Gas Permeable
Contact Lenses

POLY00176B

[redacted]

WHY YOU SHOULD USE
BOSTON ADVANCE™
Solutions

[redacted]

DIRECTIONS
BOSTON™
Cleaner

[redacted]

BOSTON ADVANCE™
Conditioning Solution

[redacted]

BOSTON ADVANCE™
Reconditioning Drops

[redacted]

Ask For
BOSTON™ ADVANCE
Solution

[redacted]

BOSTON ADVANCE SOLUTIONS
SHOULD NOT BE USED WITH
SOFT CONTACT LENSES

CAUTION: BOSTON Cleaner will irritate your eyes and must be removed from lenses by thorough rinsing after cleaning. The lenses should be conditioned by soaking in BOSTON ADVANCE Conditioning Solution for at least 4 hours (or overnight) before wearing.

[redacted]

Printed in U.S.A.

IMPORTANT
SAFETY INFORMATION

[redacted]

P 290

LB1103/10 S837
Insert - US Kits

CONFIDENTIAL

LABELING APPROVAL S837

VQT	[redacted]	Date: 1-5-89
R & D	N/A	Date: —
QA	[redacted]	Date: 1-10-89

EXHIBIT B

CONFIDENTIAL

Boston
ADVANCE
Conditioning Solution

For Rigid Gas Permeable Contact Lenses
See package insert

Wetting • Soaking • Disinfecting
1 fluid oz. (30 ml)
Sterile • Patented

DIRECTIONS:
- Wash hands with mild soap.
- Clean your lenses with BOSTON® or BOSTON ADVANCE® Cleaner. RINSE THOROUGHLY WITH FRESH TAP WATER, then place lenses in storage case and fill the case with BOSTON ADVANCE® Conditioning Solution. Soak for at least 4 hours for overnight before wearing.
- After removing the lenses from the storage case, reapply fresh BOSTON ADVANCE® Conditioning Solution if desired and insert.
- Clean interior of storage case with hot water and air dry. Completely replace solution every day.
- To avoid contamination, never touch the dropper tip or the container with your hands or to any surface.
- Discard solution 90 days after opening. Record date opened in space below. See package insert for details.

Date opened:

EXHIBIT B

POLY00176l

P 2881

Boston Advance
Label 200
Bott. Pack

L80094/03 LABELING APPROVAL 59215

MKT		Date: 4-26-89
R & D	N/A	Date: —
QA	G. Provencher	Date: 4-25-89
RA	Ellen M Beucler	Date: 4-25-89
Legal	By N/A	Date: —
Item No.	N/A	Supercedes —

8/20/37

L60094/01 LABELING APPROVAL # P 345

MKT	N. Caruso	Date: 6-21-89
R & D	N/A	Date: —
QA		Date:
RA		Date: 6/23/89
Legal	N/A	Date: —
Item No.	N/A	Supercedes —

- 800 %
Label-30ml BOSTON ADVANCE™ Conditioning Soln. - Bull-Starter Kit
- L60094/01 51345

PMS 072 Blue, PMS 874 Gold

P 2883

P.21/37

BOSTON ADVANCE™ Conditioning Solution

For Fluoro Silicone Acrylate and Silicone Acrylate Rigid Gas Permeable Contact Lenses (As listed)

DIRECTIONS FOR USE:

1 Wash hands thoroughly.

2 Remove lenses from storage case, reapply fresh BOSTON ADVANCE Conditioning Solution if desired and insert.

3 Thoroughly clean interior of storage case with hot water and air dry. Completely replace solution prior to storing lenses every time. Soak for at least 4 hours or overnight before wearing.

4 To avoid contamination, always keep bottle tightly closed when not in use.

5

6

FRONT

POLY001839

120 ml US Trade / Bulk Pack
Boston Advance Cond. Sol.
Print F+B

PMS 072 Bl
Black

BOSTON ADVANCE™ Conditioning Solution

DESCRIPTION:
BOSTON ADVANCE Conditioning Solution has been specifically formulated for use with fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses. It contains a patented hydrophilic polyelectrolyte, and a cationic cellulose derivative polymer. As a wetting agent, that binds to the surface of the lens enhancing wettability and maintaining surface ionic charges. It is a sterile, buffered, slightly hypertonic solution with polyelectrolyte properties (Sodium and edetate disodium dihydrate as preservatives).

ACTIONS:
BOSTON ADVANCE Conditioning Solution is a new formula that optimizes the wettability characteristics of rigid gas permeable contact lenses. It also reduces friction against the corneal and harnesses particulate matter that may cause irritation and discomfort. BOSTON ADVANCE Conditioning Solution contains a new disinfecting agent which is effective in destroying harmful microorganisms on the surface of rigid gas permeable lenses stored and in contact lens cases.

INDICATIONS:
BOSTON ADVANCE Conditioning Solution is indicated for disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses as listed in the labeling.

WARNINGS:
This solution is not for use with soft lenses. Do not use this solution if you are hypersensitive to any components of this product. To avoid contamination, never touch the dropper tip of the container with your hands or to any surface.

Contact lenses and solutions, if not handled properly can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and loss of vision may result from using contaminated solutions or from wearing contaminated or damaged contact lenses. Rinsing and then rubbing the lens with solution, before each removal, is recommended by some eye care professionals. BOSTON ADVANCE Conditioning Solution will be discussed further in class.

If you are wearing antibiotics ointments near lenses, it is extremely important to follow the patient care guide and your eye care professional's instructions for the care of both your lenses and lens care products, in order to maintain good ocular health.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follows your eye care professional's directions and all labeling instructions for proper use of your lenses and lens care products.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.

All contact lens wearers should see their eye care professional as directed. If your lenses are not extended wear/prescribed wear, your eye care professional may prescribe more frequent visits.

PRECAUTIONS: To ensure proper hygiene and handling of contact lenses and contact lens solutions, always follow lens directions carefully.

- Never reuse this solution
- Always keep the bottle tightly closed when not in use.
- Always wash your hands before handling your lenses.
- After inserting your lenses, always thoroughly clean the footpiece of the storage case with hot water and air dry. Consistently replace solution prior to storing lenses every day.
- Store solutions at room temperature.
- Use before expiration date on the container
- Always use proper hygiene and handling procedures. If not handled properly, contact lenses and contact lens solutions can become contaminated by common bacteria.
- SOAK LENSES IN BOSTON ADVANCE CONDITIONING SOLUTION, NEVER SOAK LENSES IN SALINE OR BOSTON ADVANCE CLEANER.
- ALWAYS RINSE LENSES THOROUGHLY WITH FRESH RUB WASH AFTER CLEANING WITH BOSTON OR BOSTON ADVANCE CLEANER. CONDITION LENSES WITH BOSTON ADVANCE CONDITIONING SOLUTION, SOAK FOR AT LEAST 4 HOURS (OR OVERNIGHT) BEFORE WEARING.
- KEEP OUT OF REACH OF CHILDREN.

The following problems may occur:

- Eyes stinging, burning, itching sensation
- Excessive watering (tearing) of the eyes
- Unusual eye sensitivity
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light unbearable
- Dry eyes

If you notice any of the above conditions, immediately remove and examine the lenses. If the problem stops and the lenses appear to be undamaged, thoroughly clean, rinse and disinfect the lenses and reinsert. If the problem continues or a lens appears to be damaged, immediately contact your eye care professional.

HOW SUPPLIED:
BOSTON ADVANCE Conditioning Solution is supplied in sterile 4 fluid ounce (120 ml) and one fluid ounce (30 ml) bottles. Bottles are shrink-wrapped with tamper-evident neckbands or packaged in tamper-evident cartons. The packet are marked with a lot number and expiration date.

LENSES:
BOSTON ADVANCE Conditioning Solution is indicated for use with:
Fluoro Silicone Acrylate lenses:
BOSTON® EQUALITY™
Silicone Acrylate Lenses:
BOSTON®, Menicon®, Paragon CRT®, Optacryl®, Optacryl HEP®, Optacryl HDK®, Optacryl HDS®, Optacryl HDT®, Optacryl HDT ELITE®

BOSTON Solutions should not be used with soft contact lenses.

FOR YOUR PROTECTION:
Success and comfort with contact lenses depend on proper care and handling. Follow the directions and labeling instructions for the solutions you use. Consult your eye care professional if you have any questions about your lenses or lens care products.

See your Eye Care Professional frequently.

Made in the USA
Manufactured for:
Polymer Technology Corporation
Wilmington, MA 01887
U.S. Patent No. 4,820,352

BACK

LBloM1101	LABELING APPROVAL 59181	
MKT	[signature]	Date: 5-2-90
R & D	N/A	Date: —
QA	[signature]	Date: 4-30-90
RA	[signature]	Date: 4-25-90
Legal By	N/A	Date: —
Item No.	N/A	Supercedes —

POLY001838

15a

EXHIBIT C

POLYMER TECHNOLOGY CORPORATION
[LOGO] 100 RESEARCH DRIVE • WILMINGTON
(608) 658-6111 • MASSACHUSETTS

September 14, 1989

RE: PMA Application
for the BOSTON™ Cleaner II

FDA
Center for Devices and Radiological Health
PMA – Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Sirs:

Enclosed herein, please find six (6) copies of the original PMA Application for the BOSTON™ Cleaner II for use in the care regimen for fluoro-silicone-acrylate and silicone-acrylate rigid gas permeable contact lenses.

Generic Name: Cleaning Solution For Rigid Gas Permeable Contact Lenses

Trade Name: The BOSTON™ Cleaner II

The BOSTON™ Cleaner II is indicated for daily or periodic cleaning of fluoro-silicone-acrylate and silicone-acrylate rigid gas permeable contact lenses. In addition, when combined with the BOSTON™ Conditioning Solution or the BOSTON™ Conditioning Solution II as in the BOSTON™ Care System, the system is proven to be an effective disinfecting agent. The BOSTON™ Cleaner II is available in 5 mL, 10 mL, 15 mL and 30 mL units. The shelf-life of this product is seven (7) months. Shelf-like extensions and qualifications of alternate bottle resins

will be performed in accordance with 1985 FDA Solution Guidelines.

During the development of this product the BOSTON™ Cleaner II was referred to as the SPD-KST1 Lipid Cleaner. This application and accompanying reports contain references to both names. According to 21 CFR 25.23 (c) this product is excluded from the environmental impact requirement.

This application is sponsored by Polymer Technology Corporation of Wilmington, Massachusetts. The manufacturing site of the BOSTON Cleaner II is Bausch & Lomb Solutions Plant in Greensville, South Carolina.

CONFIDENTIALITY

The information contained in this document is exempt from disclosure pursuant to section 812.38 of Title 21 of the Code of Federal Regulations and to Section 552 of Title 5 of the United States Code. In addition, specific information marked CONFIDENTIAL is considered to be Proprietary Information belonging to Polymer Technology Corporation which may not, under any circumstances, be disclosed.

If you should require additional information or have questions, please do not hesitate to contact me.

Sincerely,

/s/ Ellen M. Beueler
Ellen M. Beueler
Clinical and Regulatory
Affairs Associate

emb

EXHIBIT D

POLYMER TECHNOLOGY CORPORATION
[LOGO] 100 RESEARCH DRIVE • WILMINGTON
(608) 658-6111 • MASSACHUSETTS

November 3, 1988

RE: PMA Application
for the BOSTON™ Conditioning
Solution II and The BOSTON™
Reconditioning Drops II.

FDA
Center for Devices and Radiological Health
PMA – Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Sirs:

Enclosed herein, please find six (6) copies of the PMA Application for the BOSTON™ Conditioning Solution II and the BOSTON™ Reconditioning Drops II when used as the care regimen for rigid gas permeable contact lenses.

Generic Name:	Wetting and soaking solution for rigid gas permeable contact lenses
Trade Name:	The BOSTON™ Conditioning Solution II and The BOSTON™ Reconditioning Drops II

The BOSTON™ Conditioning Solution II and the BOSTON™ Reconditioning Drops II, hereafter referred to as the BOSTON CJP1 Solutions, are designed to be effective conditioning and rewetting agents for the care and maintenance of rigid gas permeable contact lenses. In

addition, when combined with the BOSTON™ Cleaner as in the BOSTON™ Care System, the conditioner is proven to be an effective disinfecting agent. The conditioning solution is intended for wetting and soaking the contact lenses. The reconditioning drops are intended to be instilled directly into the eye to enhance lens wettability characteristics and reduce friction against the cornea while the lens is being worn by the patient.

These solutions are similar to the currently marketed BOSTON™ Conditioning Solution and BOSTON™ Reconditioning Drops. The difference is a decrease in the viscosity and a change in the preservative system from chlorhexidine gluconate (CHG) to polyaminopropyl biguanide (PAPB). This preservative is also referred to as polyhexamethylene biguanide (PHMB) or polyhexamethylene diguanide (PHMD). According to 21 CFR 25.23 (c) this product is excluded from the environmental impact requirement.

This application is sponsored by Polymer Technology Corporation of Wilmington, Massachusetts. The manufacturing site of the BOSTON CJP1 Solutions is Bausch & Lomb Solutions Plant in Greenville, South Carolina.

If you should require additional information or have questions, please do not hesitate to contact me.

Sincerely,

/s/ William J. Gleason (emb)
William J. Gleason, O.D.
Director, Clinical and
Regulatory Affairs

emb

EXHIBIT E

[LOGO]
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

William J. Gleason, O.D.
Director, Clinical and Regulatory Affairs
Polymer Technology Corporation
100 Research Drive
Wilmington, Massachusetts 01887

RE: P820070/S14
THE BOSTON™ Conditioning Solution and
THE BOSTON™ Reconditioning Drops
Filed: November 9, 1988
Amended: April 24, and 25; and
May 3, 23, and 25, 1989

Dear Dr. Gleason:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval to decrease the viscosity and change the preservative system from chlorhexidine gluconate to polyaminopropyl biguanide for the above referenced devices. THE BOSTON™ Conditioning Solution, as modified, will be marketed under the trade name BOSTON™ Conditioning Solution II and supplied in 30 ml and 120 ml plastic

bottles. THE BOSTON™ Reconditioning Drops, as modified, will be marketed under the trade name BOSTON™ Reconditioning Drops II and supplied in a 10 ml plastic bottle.

The BOSTON™ Conditioning Solution II is indicated for disinfecting and soaking after cleaning and rinsing of silicone-acrylate and fluoro-silicone-acrylate rigid gas permeable contact lenses (as listed in the labeling). The BOSTON™ Reconditioning Drops II is indicated for use directly in the eye to lubricate and rewet silicone-acrylate and fluoro-silicone-acrylate rigid gas permeable contact lenses (as listed in the labeling) during lens wear.

Based upon the information submitted, the PMA supplement is approved subject to the conditions described in the "Conditions of approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

The expiration dating for the BOSTON™ Conditioning Solution II and BOSTON™ Reconditioning Drops II has been established and approved at 6 months. This is to advise you that the protocol used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.38(a)(8).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

All required documents must be submitted in triplicate, unless otherwise specified, to the address below and shall reference the above PMA number to expedite processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have any questions concerning the approval of this supplemental application, please contact Ms. Alice Yoza or Mr. David M. Whipple at (301) 427-7940.

Sincerely yours,

/s/ Richard E. Lippman
Richard E. Lippman,
O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure 1

CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the Food and Drug Administration (FDA), Center for

Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Advertisement. No advertisement and other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If FDA has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

Premarket Approval Application (PMA) Supplement. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or for which FDA has advised in an advisory opinion or in correspondence in accordance with 21 CFR 814.39(e) that an alternate submission is permitted. A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices (51 FR 26342) published in the Federal Register of July 22, 1986.

Postapproval Reports. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. *Two copies* identified as *"Annual Report"* and bearing the applicable PMA reference number are to be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

Adverse Reaction and Device Defect Reporting. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit *3 copies* of a written report identified as an *"Adverse Reaction Report"* or *"Device Defect Report"*, as applicable, to the Food and Drug Administration, Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20910 *within 10 days* after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable in the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occuring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that *could not* cause or contribute to death or

serious injury but *are not* correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

Reporting under the Medical Device Reporting (MDR) Regulation. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including *in vitro* diagnostic devices, report to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that

the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to reoccur.

The conditions of approval accompanying PMA approval orders may require that the same events subject to reporting under the MDR Regulation must also be included in periodic reports to the PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the conditions of approval for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Device Monitoring Branch (HFZ-343)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910
Telephone (301) 427-7500

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and a FDA publication entitled, "An Overview of the Medical Device Reporting Regulation", are available by written request to the above address or by telephoning (301) 427-8100.

EXHIBIT F

[LOGO]
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAY 3 1990

Ms. Ellen M. Beucler
Clinical and Regulatory Affairs Associate
Polymer Technology Corporation
100 Research Drive
Wilmington, Massachusetts 01887

RE: P890054
BOSTON™ Cleaner II
Filed: September 15, 1989
Amended: November 24, 1989; and February 24, March 23, and April 24, 1990

Dear Ms. Beucler:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the BOSTON™ Cleaner II. This device is indicated for use to clean fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses before conditioning (wetting, soaking, disinfecting). The solution is to be marketed in 5mL, 10 mL, 15 mL and 30 mL bottle sizes. The PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

Expiration dating for this device has been established and approved at 7 months. This is to advise you that the protocol used to establish this expiration dating is considered an approval protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. In addition, the notice will state that a copy of all approved labeling (which may be a draft of the final labeling) is available for public inspection at the CDRH. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

All required documents must be submitted in triplicate, unless otherwise specified, to the address below and shall reference the above PMA number to expedite processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850-4302

If you have any questions concerning this approval order, please contact Ms. Eleanor M. Felton or Mr. David M. Whipple at (301) 427-1080.

Sincerely yours,

/s/ D R West
for Robert L. Sheridan
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCLOSURE 1

REVISED: September 12, 1989

CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 1390 Piccard Drive, Rockville, Maryland 20850.

Advertisement. No advertisement and other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device.

If FDA has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

Pre-market Approval Application (PMA) Supplement. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or for which FDA has advised in an advisory opinion or in correspondence in accordance with 21 CFR 814.39(e) that an alternate submission is permitted. A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices (51 FR 26342) published in the Federal Register of July 22, 1986.

Postapproval Reports. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. *Two copies* identified as *"Annual Report"* and bearing the applicable PMA reference

number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Drive, Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

The "Conditions of Approval" accompanying PMA approval orders may require that the same events subject to reporting under the MDR Regulation must also be included in periodic reports to the PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and

identified with the PMA reference number to the following office:

Device Monitoring Branch (HFZ-343)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850
Telephone (301) 427-1144

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation", are available by written request to the above address or by telephoning (301) 427-1140.

Supreme Court, U.S.
FILED
JUL 31 1997
CLERK

No. 97-26

In The Supreme Court Of The United States

OCTOBER TERM 1997

DEBORAH EDDY AND THOMAS EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG, INC. AND DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

BRIEF OF RESPONDENTS POLYMER TECHNOLOGY CORPORATION AND THRIFT DRUG, INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

KERRY A. KEARNEY
REED SMITH SHAW & McCLAY LLP
435 Sixth Avenue
Pittsburgh, Pennsylvania 15219
(412) 288-3046

Counsel of Record for Respondents Polymer Technology Corporation and Thrift Drug, Inc.

LANTAGNE LEGAL PRINTING
801 East Main Street Suite 100 Richmond, Virginia 23219 (800) 847-0477

QUESTION PRESENTED

I.

Is a tort claim preempted under 21 U.S.C. § 360k of the Medical Device Amendments to the federal Food, Drug and Cosmetics Act where Petitioners' only claimed product defect is that the labeling required by the Food and Drug Administration ("FDA") for a Class III pre-market approved ("PMA") device allegedly makes the product unsafe and defective?

PARTIES TO THE PROCEEDING

The parties to the proceeding below were the Petitioners Deborah Eddy and Thomas Eddy and the Respondents Polymer Technology Corporation, Thrift Drug, Inc., and Dr. James H. Letham, O.D.

RULE 29.6 LISTING

Bausch & Lomb, Incorporated is the parent corporation of Polymer Technology Corporation. Thrift Drug, Inc. is a subsidiary of J.C. Penney Company, Inc. Neither Polymer Technology Corporation nor Thrift Drug, Inc. has any nonwholly owned subsidiaries.

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STATEMENT OF THE CASE

The contact lens cleaning products at issue in this case, Boston Advance® Conditioning Solution ("Solution") and Boston Advance® Cleaner ("Cleaner") are classified as Class III pre-market approved ("PMA") medical devices by FDA. Both are manufactured by Polymer Technology Corporation ("Polymer"). As part of the approval process for the Cleaner and Solution, FDA referred Polymer's PMA application to the FDA's Ophthalmic Devices Panel of the Center of Devices and Radiologic Health for review of labeling by experts in ophthalmology. FDA granted pre-market approval, finding the products safe and effective with certain FDA-approved labeling. Reproduced Record ("R.") 44a. The FDA-approved labeling for the Cleaner instructed the user to "remove all traces of Boston Advance Cleaner by thoroughly rinsing with fresh tap water." R. 49a. The approved instructions for the Solution directed the user to "rinse thoroughly with fresh tap water, then place lenses in storage case and fill the case with Boston Advance Conditioning Solution." R. 45a, 52a.

On September 21, 1992, Petitioners Deborah and Thomas Eddy filed suit in Allegheny County, Pennsylvania against the prescribing

optometrist, Polymer and Thrift Drug, Inc. ("Thrift"). Petitioners claimed that the Solution and Cleaner were defective only because the labeling instructs the user to employ "tap water rinsing:"

> Plaintiffs claim a defect in the product directions and instructions for use . . . which direct and instruct the user "to remove all traces of cleaner by thoroughly rinsing with fresh tap water" without identifying tap water as a potential source of contamination; and in failing to adequately inform or warn users of the risk of contamination from the use of tap water to rinse the lenses.

Petitioners' Complaint at ¶¶ 14(g)-(h). R. 8a.

Deborah Eddy alleges that she developed an acanthamoeba eye infection because she rinsed her lenses in contaminated tap water. Petitioners' claims are based on theories of negligence, strict liability and breach of implied warranty.

Under Section 360k(a) of the Medical Device Amendments to the Food, Drug and Cosmetics Act ("MDA"), state claims are preempted where the claim imposes "requirements" different than or in addition to FDA requirements governing the

manufacture, labeling and distribution of a medical device. 21 U.S.C. § 360k(a) provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> (1) which is different from, or in addition, to any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

On October 20, 1994, a Pennsylvania trial court granted summary judgment in favor of Respondents Polymer and Thrift, finding that the MDA expressly preempted Petitioners' state tort claims. On December 5, 1995, the Pennsylvania Superior Court affirmed. The Pennsylvania Supreme Court denied Petitioners' request for discretionary review on March 31, 1997.

REASONS FOR DENYING THE WRIT

There is no decision from the Pennsylvania Supreme Court in this case. As a result of the denial, without opinion, by the Pennsylvania Supreme Court of discretionary review, Petitioners and this Court have no basis to know why the Pennsylvania Supreme Court acted. Despite the fact that Petitioners cannot inform this Court of the actual basis for the decision in Eddy v. Polymer, they suggest that an earlier Pennsylvania Supreme Court decision, Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), cert. denied, 117 S.Ct. 1432 (1997) and 117 S.Ct. 1695 (1997), is in conflict with other state court decisions. Certiorari was denied in Green and review of Green cannot form the basis for grant of Certiorari in this case.

Secondly, review should be denied because the result in Eddy is consistent with Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996). Lohr involved a 510(k) device rather than the Class III PMA device at issue here. Further, in Lohr, there was no FDA "requirement" in conflict with the claimed defect. The Eddy case involves a direct conflict between the defect claimed by Petitioners -- tap water rinsing is dangerous -- and the labeling required by FDA -- tap water rinsing is proper. This case is analogous to a

long line of pre-Lohr preemption cases involving tort claims arising from tampon labeling requirements which culminate with the post-Lohr case, Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997). In these tampon warning cases, MDA preemption of failure to warn claims has been found because of a direct conflict between the tampon labeling required by FDA and plaintiff's claimed labeling defect.

A. This Court Should Deny Certiorari Because The Basis Of The Eddy Ruling Is Unknown.

The Pennsylvania Superior Court affirmed the grant of summary judgment in the Eddy case on December 5, 1995, four and a half months before this Court's decision in Medtronic, Inc. v. Lohr. The Pennsylvania Supreme Court denied review without opinion on March 31, 1997, almost one year after Lohr was decided. Polymer and Thrift submit that this Court should not grant Certiorari since this Court cannot know why the Pennsylvania Supreme Court denied review. Clearly, the Pennsylvania Supreme Court had the benefit of Lohr when it denied review in Eddy.

Petitioners suggest that this Court should grant review because the November 22, 1996 Pennsylvania Supreme Court decision in Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), cert. denied, 117 S.Ct. 1432 (1977) and 117 S.Ct. 1695 (1997), is in conflict with Lohr and with decisions of certain state courts from Arizona, California, Michigan, New York and Illinois. Respondents Polymer and Thrift submit, however, that Green v. Dolsky supplies no basis for review in the Eddy case. Further, Green has already been submitted to this Court for review and Certiorari was denied.

Even if Green were relevant, Petitioners misrepresent the holding of the Pennsylvania Supreme Court in Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), cert. denied, 117 S.Ct. 1432 (1997) and 117 S.Ct. 1695 (1997). Only certain claims were found preempted for the Class III, PMA device at issue in Green. Other claims were not found preempted by the court in Green. The court in Green undertook a detailed review of Lohr and did not make a wholesale pronouncement that all claims were preempted for PMA devices, despite the Eddy Petitioners' contrary and misleading suggestion to this Court. Clearly, the court in Green found that failure to warn labeling claims were preempted for Class III PMA devices,

although it allowed other claims for PMA devices to proceed to trial.

Polymer and Thrift submit that there is no conflict between Eddy and other state court decisions on preemption since the basis of the Pennsylvania Supreme Court's ruling in Eddy is not known. Further, Green does not stand for the proposition asserted by Petitioners. Green does not find all PMA claims preempted but instead undertakes a careful analysis of Lohr, finding certain claims preempted and others not preempted. This Court should deny the Writ because the basis of decision in Eddy is not known.

B. The Result In The Eddy Case Is Consistent With This Court's Reasoning In Medtronic, Inc. v. Lohr.

To determine whether 28 U.S.C. § 360k invalidates the Eddy product liability claim, a court must determine (1) whether the Eddys' Complaint would establish "requirements" relating to the safety and effectiveness of the contact lens Solution and Cleaner; (2) whether there is an FDA requirement applicable to the contact lens Solution and Cleaner; and (3) whether the labeling "required" in the Eddy

Complaint is "different from or in addition to" the FDA labeling requirement. In finding no preemption for the Lohr 510(k) device, the Lohr court found that there were no FDA requirements which conflicted with the Lohr Petitioners' claim of product defect.[1]

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1 Respondents Polymer and Thrift submit that the determination by FDA's Ophthalmic Devices Panel that tap water rinsing should be included in the labeling for gas permeable contact lens Solution and Cleaner is a "specific requirement[s] applicable to the particular device under the act." As such, FDA's own regulations clearly demonstrate that the Eddy claim should be preempted under 21 C.F.R. § 808.1(d) which provides:

> (d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other **specific requirements applicable to a particular device under the act**, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. . . .

Emphasis added.

21 C.F.R. § 808.1(d)(1) relied on by the Eddy Petitioners at page 7 of their brief does not apply to the issues raised in Eddy since FDA-mandated labeling (tap water rinsing is proper) does not conflict with any

Continued on following page

Respondents Polymer and Thrift submit that the result in Eddy is consistent with Lohr because Eddy involves the PMA process rather than 510(k) review, because FDA has set a labeling requirement for this Solution and Cleaner, and because the labeling requested by Petitioners (no tap water rinsing) is "different from" and "in addition" to the FDA-required labeling (tap water rinsing proper).

This Court should deny the Writ because Eddy is consistent with Lohr.

C. The Result In Eddy Is Consistent With And Not In Conflict With Other Decisions.

The Eddy case involves a direct conflict between FDA requirements and the claimed defect. Petitioners claim only one defect in the contact lens Solution and Cleaner: labeling which permits "tap water rinsing" makes the product unsafe and defective. FDA determined as part of the PMA process that the

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"state or local requirement of general applicability . . ." as required by § 808.1(d)(1).

Solution and Cleaner are "safe and effective" with labeling which instructs the user to employ "tap water rinsing."

Nowhere have Petitioners disputed that the labeling used by Polymer is required by FDA. Joint compliance is impossible. No case decided since Lohr has addressed this narrow issue. Thus, there is no conflict between Eddy and any other decision.

Furthermore, the result in Eddy is consistent with a line of pre-Lohr[2] and post-Lohr cases

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2 The tampon cases decided prior to Lohr include the following, all of which find labeling claims preempted: Moore v. Kimberly-Clark Corp., 867 F.2d 243, 245 (5th Cir. 1989) (affirming grant of summary judgment in favor of tampon manufacturer on plaintiff's failure to warn claim because FDA regulations "outline the liability and warning requirements with respect to TSS") and National Bank of Commerce of ElDorado v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) (tampon warning claims preempted; but finding design and manufacture claims not preempted). Accord Bejarano v. International Playtex, Inc., 750 F. Supp. 443 (D. Idaho 1990); Krause v. Kimberly-Clark Corp., 749 F. Supp. 164 (W.D. Mich. 1990); Northrip v. International-Playtex, Inc., 750 F. Supp. 402 (W.D. Mo. 1989); Lindquist v. Tambrands, Inc., 721 F. Supp. 1058 (D. Minn. 1989); Cornelison v. Tambrands, Inc., 710 F. Supp. 706 (D. Minn. 1989); Meyer v. International Playtex, Inc., 724 F. Supp. 288

Continued on following page

dealing with tampons and the FDA-required toxic shock warning. In Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997), plaintiffs claimed that Class II tampons were defective in that they did not provide sufficient warning of the danger of toxic shock syndrome. The Ninth Circuit Court of Appeals in Papike found the claim preempted since Tambrands had provided the label warning required by FDA. The court in Papike determined that preemption was consistent with the U.S. Supreme Court's decision in Lohr because of the specific labeling requirement for tampons.

Respondents submit that this Court should deny the Writ because there is no conflict

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(D.N.J. 1988); Lavetter v. International Playtex, Inc., 706 F. Supp. 722 (D. Ariz. 1988); Rinehart v. International Playtex, Inc., 688 F. Supp. 475 (S.D. Ind. 1988); Edmondson v. International Playtex, Inc., 678 F. Supp. 1571 (N.D. Ga. 1987); Stewart v. International Playtex, Inc., 672 F. Supp. 907 (D.S.C. 1987); Lulov v. Tambrands, Inc., 198 A.D.2d 479, 604 N.Y.S.2d 206 (App. Div. 1993); Poloney v. Tambrands, Inc., 412 S.E.2d 526 (Ga. 1991); Berger v. Personal Prods., Inc., 797 P.2d 1148 (Wash. 1990), cert. denied, 499 U.S. 961 (1991).

between Eddy and a long line of federal court labeling cases dealing with tampons.

D. There Are No Important Issues At Stake In This Case.

This Court should deny review because this case does not present any important issues. The case does not present a basis for review of preemption in the PMA process. [3] This case presents a narrow

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3 Several federal cases have addressed the issue of MDA preemption since the Supreme Court's decision in Lohr. Respondent Polymer and Thrift submit that the result in Eddy is consistent with each of these post-Lohr federal cases. Committee of Dental Amalgam Mfrs. and Distribs. v. Stratton, 92 F.3d 807 (9th Cir. 1996) (no preemption for Class I and Class II devices), cert. denied, 117 S.Ct. 754 (1997); Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324 (4th Cir. 1996) (on remand from U.S. Supreme Court, no preemption for Class III penile implant approved by FDA through 510(k) substantial equivalence review, even though device was tested through IDE process prior to submission of the 510(k) notification); Feldt v. Mentor Corp., 95 F.3d 4 (5th Cir. 1996) (on remand from the U.S. Supreme Court, no MDA preemption for Class III 510(k) device); Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090 (6th Cir. 1997), cert. filed, 65 U.S.L.W. 3755 (May 1, 1997) (on remand from the U.S. Supreme Court, affirming summary judgment based on MDA preemption for Class III pacemaker reviewed through

Continued on following page

issue dealing with a direct conflict between FDA-required labeling and the labeling defect claimed by Petitioners.

Because this case was decided by an intermediate appellate court in Pennsylvania without the benefit of any decision by the highest court of the state, because it involves a narrow issue and because it is consistent with all post-Lohr federal

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the IDE process where components of the product were submitted to FDA through the 510(k) substantial equivalence review); Reeves v. AcroMed Corp., 103 F.3d 442 (5th Cir. 1997) (on remand from the United States Supreme Court, finding no preemption for Class III metal bone implant submitted to FDA through 510(k) substantial equivalence review.) See Berish v. Richards Med. Co., 937 F. Supp. 181 (N.D. N.Y. 1996) (finding MDA preemption for all claims for Class III IDE hip prosthesis, except claims for failure to follow FDA regulations); Niehoff v. Surgidev Corp., 1997 WL 336346 (D. Ky. June 19, 1997).

decisions, there is no important federal issue raised in this case sufficient to justify the grant of Certiorari.[4]

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[4] In the absence of federal court precedent on an issue dealing with the interpretation of federal law, Petitioners suggest that this Court should find a conflict based on state court decisions from Illinois (in the Seventh Circuit); Arizona (in the Ninth Circuit); California (in the Ninth Circuit); New York (in the Second Circuit); Florida (in the Eleventh Circuit) and Michigan (in the Sixth Circuit). See state court cases cited by Eddy Petitioners at pages 4, 5 of their brief. While the Supreme Court rules theoretically permit the assertion of such a conflict, Respondents Polymer and Thrift submit that this Court should deny Certiorari until the federal courts of appeal in which these states are located have looked at the issue of MDA preemption for Class III PMA Devices. With the exception of the Ninth Circuit, none of these circuits have looked at MDA preemption for PMA Class III devices. The pre-Lohr Ninth Circuit decision in Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) finds no MDA preemption for claims relating to a Class III PMA device, finding for the product at issue there were no FDA "requirements." The Kennedy Court, however, specifically approves the tampon cases in which a specific FDA-required label can support a finding of MDA preemption. Further, the Ninth Circuit in the post-Lohr tampon warning case, Papike, supra, cites Kennedy with approval. The result in Eddy is absolutely consistent with the Ninth Circuit law set forth in Kennedy and Papike, since in Eddy there is a "specific requirement applicable to the particular device." This Court should deny Certiorari based on conflicts set forth in state court decisions since

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CONCLUSION

Respondents Polymer and Thrift submit that the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

Kerry A. Kearney
REED SMITH SHAW & McCLAY LLP
James H. Reed Building
435 Sixth Avenue
Pittsburgh, Pennsylvania 15219
(412) 288-3046

Counsel for Respondents
Polymer Technology Corporation
and Thrift Drug, Inc.

Dated: July 31, 1997

Continued from previous page

this important federal issue has not been ruled on by federal courts of appeal.

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No. 97-26

In The

Supreme Court of the United States

October Term, 1996

DEBORAH EDDY AND EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION,
THRIFT DRUG, INC. AND
DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

PETITIONERS' REPLY MEMORANDUM

JOEL PERSKY, ESQUIRE
Counsel of Record

DAVID B. RODES
GOLDBERG, PERSKY, JENNINGS & WHITE, P.C.
1030 Fifth Avenue
Pittsburgh, PA 15219
(412) 471-3980

Counsel for Petitioner

Of Counsel:
HARLAN S. STONE
STONE & STONE
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219
(412) 391-2005

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
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A. The Basis of the Pennsylvania Superior Court's Judgment Is Readily Ascertainable.

The ruling of the Pennsylvania Superior Court was expressly predicated on that court's belief that pre-market approval ("PMA") by the Food and Drug Administration ("FDA") preempts all of Petitioners' state law causes of action.[1] Inability to ascertain the reasons for the Pennsylvania Supreme Court's denial of discretionary review is beside the point, as it is the decision of the Superior Court for which *certiorari* is sought.

B. The FDA Did Not "Require" Respondents Not to Warn of the Danger of Acanthamoeba Keratitis Infection from Tap Water Rinsing.

Respondents' principal argument is that the Superior Court's decision is consistent with the reasoning of *Medtronic, Inc. v. Lohr*,[2] and with the holdings of post-*Medtronic* PMA cases, because this case "involves a direct conflict between the defect claimed by Petitioners – tap water rinsing is dangerous – and the labeling required by the FDA – tap water rinsing is proper." Brief

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[1] The Superior Court explained: "a finding in favor of [appellants] on any of their alleged state tort law claims would impose additional or different requirements on [appellee] . . . whose product . . . has already received FDA approval. Such requirements are in conflict with the MDA and thus, the [appellants'] state law claims are therefore preempted." App. 4-5, quoting *Green v. Dolsky*, 641 A.2d 600, 605 (Pa. Super. 1994), *aff'd*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 2579 (1997) (brackets and ellipses in original).

[2] 116 S. Ct. 2240 (1996).

of Respondents at 4. This argument is wrong, for two reasons.

First, the FDA did not *require* the labeling at issue; it merely *approved* labeling designed and submitted by Respondent Polymer. The absence of an affirmative federal requirement renders this case starkly different from the tampon / toxic shock syndrome ("TSS") cases with which Respondents would group it. Thus, in *Papike v. Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997), the Ninth Circuit found state law mislabeling claims preempted because the FDA had "promulgated a regulation mandating the specific substantive content of the TSS warnings on tampon boxes and/or tampon package inserts." *Id.* at 740, citing 21 C.F.R. 801.430. The presence of such a specific, mandatory, substantive regulation made the case one "in which the Federal Government has weighed the competing interests . . . and implemented [its] conclusion via a specific mandate on manufacturers or producers." *Id.* at 741, quoting *Medtronic*, 116 S. Ct. at 2258.[3]

In contrast to the FDA's direct regulation of the substance of the warning at issue in *Papike*, in the present case the FDA did not affirmatively mandate or require the content of the labeling chosen by Polymer. It is instructive that the Ninth Circuit considered the specificity of the tampon labeling regulation to be the factor

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[3] *Cf. Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (finding limited statutory preemption where statute specified precise warning to be included with cigarettes).

that distinguished *Papike* from its prior holding in *Kennedy v. Collagen Corp.*[4] that the FDA's premarket approval process is *not* a "specific requirement applicable to a particular device."[5] Because the present case involves only premarket approval rather than an affirmative regulatory requirement, it is unlike the tampon cases but indistinguishable from *Kennedy* and the state court PMA cases cited in Petitioners' Petition for Writ of Certiorari.

Second, even if the FDA's approval somehow transformed Polymer's designs into federal requirements, no aspect of that approval required Respondents not to provide warnings or information regarding the risk of acanthamoeba keratitis infection. Indeed, the FDA's regulations expressly permit a manufacturer of an approved Class III medical device to make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction" without prior FDA approval. 21 C.F.R. § 814.39(d)(i). Petitioner has claimed that Respondents had a duty under Pennsylvania tort law to supply warnings and information about

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[4] 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996).

[5] "FDA regulations . . . provide that state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.' 21 CFR 808.1(d) (1995)." *Medtronic*, 116 S. Ct. at 2257. *Cf. Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, 92 F.3d 807, 813 (9th Cir. 1996), cert. denied, 117 S. Ct. 754 (1997) ("Inherent in the term "requirement" is the idea that there be a positive enactment from the FDA before preemption can be triggered.").

an adverse reaction,[6] and the applicable federal regulation allows labeling changes which would comply with that duty. Respondents' conclusion that "[j]oint compliance [with state law duties and FDA requirements] is impossible", Brief of Respondents at 10, is simply wrong.

C. This Case Raises a Recurring Issue with Important Implications for state Product Liability Law.

Respondents suggest that despite the conflict among State courts with respect to the preemptive effect of premarket approval, this Court should deny review "until the federal courts of appeal in which these courts are located have looked at the issue". Brief of Respondents at 14 n.4. However, although the MDA is a federal statute, issues concerning its preemptive effect are likely to arise more frequently in state courts than in federal courts. Most tort claims arise under state law, and because plaintiffs in product liability cases usually join local distributors or suppliers as defendants (as in this case), the federal courts have neither federal question nor diversity jurisdiction over such claims.

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[6] Respondents incorrectly assert that "Petitioners claim only one defect in the contact lens Solution and Cleaner: labeling which permits 'tap water rinsing' makes the product unsafe and defective." Brief of Respondents at 9. On the contrary, Petitioners alleged in their complaint, *inter alia*, that "the lens cleaner and the conditioning solution . . . were in a defective condition because of the lack of warning and information to accompany these products." Complaint ¶ 18 (R. 9a).

The PMA preemption issue is no less weighty because it has been addressed in state courts. The displacement of important state law product safety and compensation policies[7] implicates concerns which are central to our federal system.

Respectfully submitted,

JOEL PERSKY, ESQUIRE
Counsel of Record

DAVID B. RODES
GOLDBERG, PERSKY, JENNINGS & WHITE, P.C.
1030 Fifth Avenue
Pittsburgh, PA 15219
(412) 471-3980

Counsel for Petitioner

Of Counsel:
HARLAN S. STONE
STONE & STONE
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219
(412) 391-2005

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[7] The importance of PMA preemption as a concern of state law is illustrated by the joinder of a majority of the States as *Amici Curiae* in support of petitions for *certiorari* in two previous cases presenting the same issue. *See* Brief of Alabama, et al. in *King v. Collagen Corp.*, No. 92-1979 and in *Stamps v. Collagen Corp.*, No. 92-1989.

(5)

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In The

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Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

PETITIONERS' SUPPLEMENTAL BRIEF

JOEL PERSKY, Esquire
Counsel of Record

DAVID B. RODES
GOLDBERG, PERSKY, JENNINGS & WHITE, P.C.
1030 Fifth Avenue
Pittsburgh, PA 15219
(412) 471-3980

Counsel for Petitioners

Of Counsel:
HARLAN S. STONE
STONE & STONE
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219
(412) 391-2005

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PETITIONERS' SUPPLEMENTAL BRIEF

Petitioners file this Supplemental Brief pursuant to Supreme Court Rule 15.8 to address the December 8, 1997 Brief for the United States as Amicus Curiae ("Amicus Brief") filed in *Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405 (petition for cert. filed March 4, 1997),[1] and the proposed rule of the Food and Drug Administration ("FDA") appended thereto.[2]

Kernats presents the same issue as the present case – viz., whether the FDA's pre-market approval of a medical device results in pre-emption of state tort law with respect to the device. In its Amicus Brief (at 9, 18) the United States recognized that this is "an issue of substantial importance that has divided the lower courts," and that this division "would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." However, the United States concluded that *certiorari* is inappropriate in *Kernats* because (1) the judgment in *Kernats* is not final; (2) the judgment in *Kernats*, denying preemption, is correct in the view of the United States; and (3) the FDA is proposing a rule that bears on the issue.

The present case differs from *Kernats* in that the court below reached the opposite result, holding all of Petitioners' claims preempted, and in so doing disregarded

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[1] The United States filed its Amicus Brief in *Kernats* in response to an order of this Court inviting the Solicitor General to file a brief expressing the views of the United States. *See Kernats*, 137 L. Ed. 2d 817 (May 12, 1997).

[2] The proposed rule has since been published at 62 Fed. Reg. 65384-65388 (Dec. 12, 1997).

the FDA's longstanding interpretive regulations. Petitioners submit that, in view of these differences, the United States's recommendation against *certiorari* in *Kernats* should not control this case. Alternatively, if the Court believes that the FDA's proposed rule is sufficiently important to warrant deferral of review, the Court should remand this case for reconsideration in light of that rule.

1. The judgment in the present case is final.

The United States points out that this Court may lack jurisdiction under 28 U.S.C. § 1257 to review the judgment in *Kernats* because that judgment is interlocutory rather than final. The petitioner in *Kernats* may yet prevail on state law defenses; and if it loses on the merits, it will again have an opportunity to seek discretionary review of its federal preemption claim in the Illinois Supreme Court.

In the present case, in contrast, the effect of the Pennsylvania Superior Court's judgment, coupled with the Pennsylvania Supreme Court's denial of review, is to put Petitioners out of court forever on all of their claims. No issues remain to be decided by the lower courts, and thus there will be no vehicle for a later appeal. The judgment upon which review is sought in this case is therefore a "final judgment" for purposes of 28 U.S.C. § 1257.

2. The judgment in the present case is incorrect.

The second ground cited by the United States for recommending against *certiorari* in *Kernats* is that, although the United States disagrees with the reasoning of the lower court in that case, in its view the judgment denying preemption is correct. This reason clearly does not apply to the present case. The court below reached the opposite result to that in *Kernats*, holding that all state law causes of action are pre-empted by virtue of the FDA's pre-market approval. This result is directly contrary to the position of the United States as set forth in its Amicus Brief at 14-18. To the extent that the correctness of the judgment in *Kernats* is a factor militating against *certiorari* in that case, the incorrectness of the judgment in the present case should militate in favor of a grant of *certiorari* herein.

3. The FDA's issuance of a proposed clarifying regulation should not forestall review.

Unlike the first two grounds, the third ground proffered by the United States in opposition to *certiorari* in *Kernats* the FDA's issuance of a new proposed rule does apply to the present case. However, the proposed rule is not sufficient to warrant putting off resolution of the important issue posed in this case, for three reasons.

First, the proposed rule does not represent a departure from the FDA's prior interpretation. Rather, it is merely a restatement of the agency's long-standing and oft-repeated position. As the FDA explains:

> This proposed rule would make no change in the agency's prior or current construction of

> section 521 of the act[, 28 U.S.C. § 360k]. Rather, the rule would simply clarify and codify the agency's longstanding interpretation of the scope of section 521 of the act as generally not preempting available legal remedies, including State common law tort claims.

Appendix to Amicus Brief at 15a.[3] Although it may sometimes be appropriate to defer review until the lower courts can react to a pathbreaking new administrative interpretation, this factor does not apply where, as here, the proposed regulation reflects the same interpretation that has been available to guide the courts for nearly 20 years.[4]

Second, waiting to see if an agency can diffuse a conflict among the courts by restating its own view will render the ultimate resolution of legal questions less efficient, by requiring a second round of intermediate appeals before an issue can reach this Court. Under the practice urged by the United States, when a conflict arises among the courts on an issue of statutory interpretation, the issue would first be referred to an agency to weigh in on one side or the other, and only after a new series of suits and appeals revealed a continuing conflict would

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[3] *See also, e.g., id.* at 12a (stating that the interpretation in the proposed rule is based "primarily on the language of section 521 of the act and *the agency's past regulatory interpretation*") (emphasis added).

[4] *Cf. id.* at 4a-5a (stating that 21 C.F.R. § 808.1(d), which embodies the FDA's restrictive interpretation of 21 U.S.C. § 360k, "has remained substantially unchanged for nearly 20 years").

the courts and the parties receive the benefit of this Court's guidance.

It is significant that the FDA's proposed rule has only very recently been proposed. It will take some time before it is promulgated as a final regulation, and considerable further time before new cases in which the regulation may be considered could work their way up through the lower courts and become ripe for review in this Court. In the meantime, if the suggestion to defer review were accepted, not only the decisions for which *certiorari* is sought based on the present split among the courts, but numerous other cases that may be controlled by those decisions, would fall by the wayside. The result would be that the lower courts continue to be burdened with uncertainty about the law and that a potentially large group of litigants (on the ultimately prevailing side of the issue) would see the issue resolved too late to afford them relief.

Third, as a practical matter it is hardly to be expected that the lower courts, having divided sharply in the face of the FDA's long-term adherence to the same position it now espouses, will suddenly achieve unanimity due to the FDA's formal reaffirmation of its position. A change in position is especially unlikely in the present case, as the Pennsylvania courts have already shown a disinclination to follow the FDA's guidance on the issue at hand.[5]

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[5] Although Petitioners emphasized the FDA's regulations in the courts below, the opinions herein make no mention of those regulations.

Petitioners believe that the foregoing considerations, coupled with the undoubted importance of the issue presented herein, justify a grant of *certiorari* in this case. In the alternative, if the Court believes that lower courts' consideration of the FDA's proposed rule might eliminate the conflict or focus the issues for review, Petitioners request that the Court remand this case to the Superior Court of Pennsylvania for reconsideration in light of the proposed rule.

Respectfully submitted,

JOEL PERSKY, Esquire
Counsel of Record

DAVID B. RODES
GOLDBERG, PERSKY, JENNINGS & WHITE, P.C.
1030 Fifth Avenue
Pittsburgh, PA 15219
(412) 471-3980

Counsel for Petitioners

Of Counsel:
HARLAN S. STONE
STONE & STONE
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219
(412) 391-2005